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## BLOOD ANALYZER AND PRICKING DEVICE FOR USE IN BLOOD ANALYSIS

## Description

This invention relates to a blood analyzer for determining an analyte such [0001] as fructosamine, lactate, cholesterol or in particular glucose on minimal quantities of blood taken from a user immediately prior to analysis, with a housing body, with a blood sampling device having a pricking element, with a test means for accommodating a minimum quantity of blood, with an analyzer device comprising an electronic analyzer and with a display device, together forming a complete system that can be handled as a single unit, whereby the housing body has a pricking position assigned to the working position of the pricking element for being applied to a skin surface of a user and having a charging position designed at another location in the housing body for charging a minimal quantity of blood escaping from the previously pricked skin surface to a test means, whereby a plurality of test means and pricking elements can be inserted into the device and can be brought into a working position for performing several measurement one after the other, whereby in positioning a pricking element in its working position the pricking element can be inserted into the skin surface of a user which is brought to the pricking position and blood escaping from the skin surface, can be charged to a test means by applying the skin surface to the charging position, said test means being in a working position of the test means.

This invention thus relates to complete devices which are also known as "all-in-one" units. The test means may be designed, for example, in the form of a membrane which defines the measurement field and is wetted with the minimal quantity of blood sampled and comprises test reagents with the help of which the analysis is performed. The analysis device may operate optically, for example, preferably by reflectometry, or it may operate electrochemically.

[0003] United States Patent 5,971,941 A discloses a complete system in the sense described above whereby a cassette with unused test means in the form of strips

is inserted into a basic unit and then a particular test strip can be brought into the proper working position by means of a slide. By means of a ram, a pricking element is pushed outward via a deployment device which forms a part of the blood sampling device in order to prick the surface of a user's skin, so that capillary blood can be obtained for analysis. The pricking elements are integrated into a test strip and thus are brought into position together with the test strip. Details of how the analysis is performed cannot be obtained from this publication, however. According to another embodiment described in this publication, a disposable cylindrical attachment or insertion is described, having a pricking element and a tablet-shaped test membrane with continuous opening for the pricking element. This attachment or insert is then inserted into a holding recess of a ram arrangement which forces the pricking element outward for taking the blood sample.

[0004] According to one embodiment of German Patent 198 19 407 A1, a plurality of test means in the form of strips with pricking elements integrated into them in a manner not described there can be inserted into an analyzer and brought successively thereafter into a working position. This publication does not contain any clear-cut reference to technical feasibility.

United States Patent 4,787,398 A describes a blood sugar meter with a basic unit having a ram arrangement for deflecting a pricking element and an analyzer device and a display device. For each measurement, a replaceable unit must be attached to the basic unit, said replaceable unit comprising a pricking element and a test means in the form of a test strip to be wetted with blood. This replaceable unit is discarded after each use.

[0006] A blood analyzer known from European Patent 0 449 525 A1 also comprises an integrated blood sampling device with a pricking element. Before starting operation each time, however, a new pricking element must be manually inserted into the deployment device as part of the blood sampling device and then a test strip must be inserted into the device.

[0007] United States Patent 4,627,445 A discloses a blood sugar meter with an integrated blood sampling device. Here again however, a new replaceable unit comprising a pricking element and a test means must be mounted on a base plate and then dismantled for each measurement.

[0008] United States Patent 5,951,492 A is similar. According to this publication, a disposable unit comprises a capillary tube with a test strip provided on the end distal from the body to receive the minimal amount of blood to be taken. The capillary tube is designed with a pricking element on its distal end. Again a new disposable unit of the type described above must be installed before each measurement operation and removed after the measurement.

[0009] In addition European Patents 0 877 250 A2, 0 949 506 A2 and 0 811 843 A2 disclose non-generic blood analyzers with which a plurality of test strips may be arranged on a rotating disk as a support for the test means, whereby the test means can be brought successfully into an operating position and can be pushed out of the housing body for wetting them with a minimal quantity of blood.

[00010] United States Patents 6,228,100 B1 and 4,794,926 disclose blood sampling and pricking devices with which a number of pricking elements are arranged on a support that is rotatable with respect to a housing body. According to United States Patent 6,228,100 B1, the pricking elements are ejected radially by means of an ejector device and according to United States Patent 4,794,926, the pricking elements are oriented in the axial direction and can be activated.

[00011] Based on the related art cited above, describing an all-in-one complete device, the object of the present invention is to create a device that can be designed to be compact, i.e., saving space and can be regarded as user friendly. It should be possible to easily insert unused test means and pricking elements into the device and to remove the used one from the device.

[00012] This object is achieved according to this invention with a blood analyzer of the type defined in the preamble by the fact that the test means and the pricking

elements are arranged on a support that is rotatable with respect to the housing body and they can be inserted with it into the device and by rotating the support the test means and the pricking elements can be brought into different working positions with respect to the body of the housing.

means are arranged on a rotatable support and can thus be brought into their respective working positions by a rotating movement. When speaking above of the working positions of the test means and the pricking elements, this is understood to refer to the position or the rotational position of a test means and/or a pricking element with respect to the housing body in which it is used as intended. A pricking element is in the working position of the pricking elements when it can be moved out of this working position to execute a pricking procedure via the pricking position.

wetted in this working position by a minimal amount of blood. When speaking above of the different working positions of the test means and the pricking elements, this is understood to mean that after pricking the skin surface in the pricking position of the device, a user releases the skin surface, i.e., usually the finger from the pricking position and applies it to the charging position to transfer a minimal amount of blood to a test means. For example, the working position of the pricking elements may be in a 3 o'clock position and the working position of the test means may be in a 6 o'clock position. Various working positions of test means and pricking elements, however, can also be achieved in a single rotational position of the support by arranging the pricking elements radially, for example, and orienting the test means axially. The respective pricking position would then be provided radially on the housing body and the charging position would be provided axially on the housing body.

[00015] The use of a rotating support makes it possible to implement a compact design of the housing body. Due to the fact that the used test means and pricking elements are brought out of the working position by rotation of their support, they

automatically go in this way to a disposal position without having to provide any additional separate translatory process.

[00016] It would also be conceivable and advantageous if the test means were arranged on the same support that is to be handled manually so that the pricking elements and test means can be removed, e.g., from a transfer package as a single unit that can be handled manually and can be inserted with a single operation into the analyzer.

[00017] From the standpoint of simplified production of the test means and pricking elements, however, it has also proven advantageous if the support comprises a first support part for the test means and a second support part for the pricking elements which can be assembled to form a unit that can be handled manually, preferably assembling it at the factory so that this easily handled unit can be inserted as a whole into the device and then removed again after use. However, the separate production and provision of test means on a first support part and pricking elements on a second support part should also be included, these parts being insertable individually into the blood analyzer into their rotatable arrangement there although this requires two separate assembly operations by the user.

[00018] If various support parts are provided for the test means and the pricking elements, then it proves to be advantageous that these two support parts are coupled together in a rotationally fixed manner so that it is sufficient if a single drive of one support part or the other is provided in the interior of the analyzer. Even if the support parts are assembled to form a single unit that can be handled easily, it would also be conceivable if two separate drive devices were provided in the analyzer, which may prove to be advantageous for some applications.

[00019] According to a preferred embodiment of this invention, the support or the support parts or one of the support parts has a central recess within which is provided a drive device for the blood sampling device.

[00020] The support or the support parts or one of the support parts is preferably designed in the form of a ring and is arranged so that it can rotate about the ring center in the sense of being rotatable.

[00021] The drive for the support or the support parts can be implemented in any known manner, preferably in a compact design. Electric motor drive devices or manually operable mechanical drive devices which may be designed to be controlled by a lever or a slide have proven to be advantageous. Discrete rotational positions of the support or the support parts are preferably provided, and may be implemented either by catch means, stepping means or stop means or through a suitable design of the drive device.

[00022] It has proven to be particularly advantageous and compact if the support or the support parts have a central recess which includes a driving means or a part of a driving means for rotating the support or the support part. This driving means is advantageously designed by internal gearing that meshes with another drive wheel.

[00023] This invention includes embodiments of the blood analyzer in which the pricking elements are arranged on the support so that when in the working position, they execute a pricking movement in a radial direction with respect to the rotatability of the support as well as embodiments in which the pricking elements execute a pricking motion in the axial direction.

[00024] The arrangement of the pricking elements on the support may be implemented in various ways. According to one advantageous embodiment, a particular element is arranged in a sleeve means forming a cylindrical space before execution of a pricking operation and is held by a plunger means that is movable therein. It has proven advantageous if in this case the pricking element forms a syringe part of the plunger means which is designed as an injection molded plastic part.

[00025] It is obligatorily necessary for the pricking elements to be surrounded by a sterility barrier on the support before execution of a pricking operation, so the embodiment described above has proven advantageous because in this case the

sterility barrier may be formed by the sleeve means and the plunger means which are then closed on all sides. To keep the sleeve means germproof on the side facing away from the plunger means, i.e., to seal it so that it is germ-free and sterile, it has proven advantageous if this end is covered by a sealed film in particular. To achieve a seal between the plunger means and a wall of the cylindrical space that meets requirements, another sealing means is provided there. There may also be a connection between the wall and the plunger means which is overcome in execution of the pricking operation. Furthermore, a sealing compound may also be used there or, for example, ring-shaped bulges and steps, shoulders or recesses which cooperate with these bulges may also be provided in the other parts.

[00026] With regard to the manufacturing of the arrangement of the pricking elements on the support described here, it has proven to be advantageous if several sleeve means are joined together in a strip and the ends of the strips are joined together to form a circular shape. In this way, sleeve means can be produced in the form of endless strips, divided into sections and their ends joined to form a circular shape and thus to form a support or a support part. The sleeve means arranged in a strip may also be arranged only along a partial circle, however.

[00027] According to another embodiment, the support may have several recesses with a pricking element arranged in each. In this embodiment it has proven advantageous if the pricking elements are arranged in the axial direction based on the rotatability of the support.

[00028] It has also proven advantageous if one wall bordering the recess is designed to be deformable so that it can be deflected by a driving device of the blood sampling device together with the pricking element to execute the pricking operation. To increase deformability, zones of weakening may also be provided in the wall bordering the recess. It has also proven advantageous if the recess is designed essentially in the form of a trough or a half-shell.

[00029] In this arrangement of the pricking elements on the support, it has also proven to be advantageous if the pricking elements are accommodated in a sterile

environment before the execution of a pricking operation. In this case a sterility barrier can be formed advantageously by a film-like covering means that covers the recess. This cover can be removed directly before execution of the pricking operation or it may be designed to be very thin so that it can be pricked by the pricking element.

[00030] According to another embodiment of the blood analyzer, the pricking elements have a detachable protective cap means on their free end before the execution of a pricking operation, said cap means preferably forming a sterility barrier and ensuring sterile conditions for the free end of the particular pricking element.

In the execution of the pricking operation, the pricking element can puncture through the protective cap means. However, it would also be regarded as advantageous if the protective cap means could be released by the respective pricking element immediately before the execution of the pricking operation. This may be accomplished in an advantageous manner by slightly retracting the particular pricking element immediately before execution of the pricking operation by the fact that the protective cap means is prevented from moving together with the pricking element by a stop means or the like. It has proven advantageous if the particular protective cap means can be removed from the path of movement of the pricking element after being released from the particular pricking element so that it can be accommodated in a holding space. For example, the force of gravity or a spring means may be used for this purpose.

[00032] The arrangement of the test means on the support may also be such that the test means is axially oriented with respect to the rotatability of the support or is radially oriented.

[00033] The test means are preferably oriented axially, which means that the charging position for a skin surface usually of one finger of a user is oriented in the axial direction; if not capillary fluid paths are arranged between the charging position and the test means which is in its working position. With an alignment or orientation of the testing machines with its measurement field generally being planar or extending over an area, it has proven advantageous if the test means are provided on a disk-shaped

support part, in particular a ring disk-shaped support part, the plane of which is oriented at a right angle to the axis of rotation of the support and preferably corresponds to a plane of the respective test means.

[00034] According to another embodiment of this invention, it has proven advantageous if the charging position on the housing body is covered by a movable covering part when it is not needed and is releasable when an analysis is to be performed.

[00035] In another embodiment of this inventive idea, it has proven to be advantageous if by moving the covering part in the direction of release of the charging position, a driving device of the blood sampling device can be activated, i.e., if a triggering pressure or a tension is thereby created or an electric motor driving means is driven. It has proven to be particularly advantageous if the driving device of the blood sampling device can be activated by applying tension to a spring means.

According to a very particularly preferred embodiment of this invention it is [00036] proposed that the blood analyzer should have a manually movable adjusting element which is coupled to the driving device for the pricking element and to the rotatable support in such a way that when the adjusting element is moved, the driving device for the pricking element is activated and a rotational movement of the support is induced. This manually movable adjusting element may be, for example, in the form of a wheel, a sliding part or in a preferred manner it may also be formed by the covering part mentioned above. The coupling between the adjusting element and the driving device and/or the support may be designed in such a way that the activation of the driving device and the rotation of the support take place simultaneously. However, it would also be conceivable for these to take place in chronological succession. In particular, the coupling between the adjusting element and the driving device and/or the support could be designed so that the support is rotated during a first phase of movement in a first direction of adjustment and during a second phase of movement, which may be in the opposite direction from the first adjusting direction, for example, the driving device is activated.

[00037] To achieve a stepwise further rotation of the support, it has proven advantageous if the adjusting element can be brought during a first phase of movement in a first direction of adjustment into a driving connection with the support and during a second phase of movement it can be brought into a position opposite the direction of adjustment, i.e., in the case of a reverse movement of the adjusting element into its starting position, it can be brought out of a driving connection. In this restoring movement of the adjusting element, it may also prove advantageous if the driving device for the pricking element is thereby resettable into a starting position or resting position.

[00038] The coupling between the adjusting element and the support can be implemented in an advantageous manner via a gear drive. For example, a translatory movement or a swiveling movement can be converted to a rotational movement via toothed entraining means and the rotational movement can easily be used to drive the support. However, it would also be conceivable for the coupling between the adjusting element and the support to be implemented in some other way, e.g., by entraining means in the form of catch arrangements or the like.

[00039] It has also proven to be advantageous if the drive device for the pricking element comprises a spring that can be put under tension and released suddenly, preferably in the form of a bending spring. To apply tension to this bending spring, the adjusting element may act on a receptacle for the bending spring in particular via a gear drive and can pivot this receptacle in the plane of bending of the bending spring and thereby attention to the driving device for the pricking element, i.e., activate it.

[00040] It has proven to be especially advantageous if the bending spring can be brought into a stable position under tension beyond a dead point so that the driving device automatically remains in the activated state. It is then possible to eliminate the use of a releasable catch mechanism.

[00041] According to another independent inventive idea, a deployment device for the driving device for the pricking element can also be operated by applying a skin

surface to the pricking position. The triggering device may then be designed advantageously as a contact sensor or as a button that can be depressed.

[00042] It may prove advantageous if the triggering device is provided in an ergonomically well operable location on the housing body, in particular on the side essentially opposite the pricking position. In another embodiment of this invention, a design in which the triggering device is provided in the pricking position and can be operated by applying the skin surface that is to be pricked. In this regard, an embodiment in which the triggering device has a recess for the passage of the pricking element for execution of the pricking process is preferred.

In another embodiment of this invention it is proposed that a retraction [00043] mechanism should be provided which causes retraction of a respective pricking element directly following the pricking operation so that the skin surface of a user is pricked only briefly. Such a retraction mechanism could in the simplest case be implemented by a spring means which exerts a restoring force. Such a spring means could be designed in various ways. For example a pricking element might extend through a spiral or strip-shaped spring means so that in the execution of the pricking operation, this spring means is put under tension. However, it would also be conceivable for such a retraction mechanism to be implemented in the driving device of the blood sampling device, e.g., by a force guide or by a motorized back-and-forth movement of a driving means coupled to the pricking element. For example, if the pricking element is held on a plunger means, a retraction mechanism could also be formed by designing a spring means on the plunger element. However, the retraction mechanism could also be provided by the elastic dimensional stability of a deformable wall area which holds the pricking element directly.

[00044] The blood analyzer according to this invention can be manufactured with an essentially circular disk-shaped housing body and/or a circular disk-shaped outside contour. Thus it could be designed in particular in the manner of a watch casing, in particular in the manner of wristwatch housing and in addition could include a time

display device. At any rate, it has proven advantageous if the housing body can be worn on the wrist of a user by using a tape mounted in the housing.

In addition, this invention relates to a pricking device for taking a minimal amount of blood from the human or animal body for the purpose of analysis. This pricking device may be designed in the form of an independent instrument or integrated into the blood analyzer described above to form a complete all-in-one instrument. The discussions and descriptions of the pricking device described below and its preferred features are thus regarded as essential to the invention either separately or in combination with the blood analyzer described above and/or in any combination with these features.

[00046] This invention thus relates to a pricking device for use in taking a minimal amount of blood from a human or animal body for the purpose of analysis, comprising a housing body and a plurality of pricking elements, wherein the plurality of pricking elements is arranged in or on a support and can be inserted into the housing body together with the support and can be removed from the housing body again after use, whereby a particular pricking element in a working position can be pricked with its pointed end into a skin surface of a user brought into the pricking position on the housing body, and this invention also comprises an ejector device which acts on the pricking element in its working position.

[00047] Such a pricking device is known from German Patent 100 57 832 C1.

[00048] Other pricking devices having a plurality of pricking elements are also known from United States Patent 2002/0087056 A1 or WO 02/36010 A1.

[00049] European Patent 0 589 186 B1 describes, for example, providing the ground tip of a pricking element with a safety cap means which is manually twisted off before executing the pricking process.

[00050] According to WO 01/66010 A1, a plurality of pricking elements may be accommodated in independent compartments of a magazine, a respective opening in

the compartment being sealed by an elastic material which can be punctured in the pricking operation.

[00051] Based on a pricking device according to German Patent 100 57 832 C1 mentioned above, the object of the present invention is to improve upon the handling of the pricking element inside the housing body and to ensure effective protection of the free ends of the pricking elements without thereby making the execution of the ejection process too complicated or being associated with any great demand for space.

[00052] This object is achieved according to this invention starting from a pricking device of the type defined in the preamble such that a particular pricking element is accommodated in a holding body in at least some areas and an end section of the pricking element which forms the pointed insertable end is surrounded by a detachable safety cap means; the longitudinal dimension of the respective element with the holding body and the safety cap means amounts to ≤15 mm in the pricking direction and the safety cap means can preferably be brought out of the path of movement of the pricking element by means of an internal displacement element before execution of the pricking process, preferably across the pricking direction.

[00053] As indicated above, the pricking device may be integrated into a blood analyzer so that the following is also regarded as inventive: a blood analyzer for determining an analyte such as fructosamine, lactate, cholesterol or especially glucose on minimal amounts of blood taken from a user immediately prior to that, comprising a housing body, a blood sampling or pricking device having a pricking element and an ejector device for the pricking element, comprising a test means for receiving a minimal amount of blood, with an analyzer device comprising an electronic analyzer and with a display device forming a complete system that can be handled as a single instrument, whereby the housing body has a pricking position associated with the working position of the pricking element for bringing a skin surface of a user in contact with the pricking element and a charging position which is provided in particular on another location on the housing for charging a minimal amount of blood that is escaping from the previously pricked skin surface onto a test means, whereby a plurality of test means and pricking

elements can be inserted into the device accordingly, the test means and pricking elements being suitable for performing several measurements in succession in a working position, whereby when a pricking element is positioned in its working position, the pricking element can be used to prick the skin surface of a user, said skin surface having been brought in contact with the pricking position, so that blood escaping from the skin surface can be charged to a test means by applying the skin surface to the charging position, which is in a working position of the test means, whereby the blood analyzer is further designed so that a respective pricking element is accommodated in at least some areas in a holding body and the end section of the pricking element forming the pointed insertable end is surrounded by a detachable safety cap means; the length dimension of the respective pricking element with the holding body and the safety cap amounts to ≤15 mm in the pricking direction, and the safety cap means can be brought out of the path of movement of the pricking element by means of a displacement element inside the device before execution of the pricking operation, preferably across the pricking direction.

Due to the fact that a respective element is accommodated in a holding body which may be in particular a plastic injection molded part which is integrally molded onto the pricking element, an extensive miniaturization of the pricking element to a maximum dimension of 15 mm, in a preferred embodiment max. 14 mm and in particular max. 13 mm can be achieved, whereby the length dimension also includes the holding body and the safety cap means. The safety cap means inside the pricking device is removable from the path of movement of the pricking element immediately before the execution of the pricking operation. For example, the respective safety cap means could first be pulled away from the pricking element in the pricking direction so that it exposes the free end of the pricking element so that it can be brought to the side preferably across the pricking direction and can be brought to the side automatically by means of a displacement element to then be able to execute the pricking operation. It would also be conceivable for the respective safety cap means to remain initially in its position and for the pricking element to be retracted slightly in the direction opposite the

direction of pricking so that the free end of the pricking element is released from the safety cap means.

end of the pricking element independently of the production of the holding body, in the mean time it has proven advantageous from the standpoint of manufacturing technology, especially in view of the desired miniaturization, if the safety cap means is also integrally molded on the pricking element, preferably in the same operation together with the holding body. In such a case, the safety cap means can show a transition to the holding body in one piece by way of a section which forms a weakened area or an intended breaking area. This simplifies handling of the pricking elements directly following their manufacture.

[00056] Although the section forming the weakened area or the intended breaking area could be detachable by twisting off the safety cap means, but following the discussion above, it has proven more advantageous if the section forming the weakened area or intended breaking area can be broken in response to tensile stress in the longitudinal direction of the respective pricking element, i.e., in the pricking direction.

type of displacement means, e.g., in the form of a ram or sleeve, by first pulling it off the pricking element in the pricking direction or, as already mentioned, the pricking element could be moved backward in the direction opposite the pricking direction and thereby removed from the safety cap means. According to an especially preferred embodiment of this invention, the safety cap means is releasable from the pricking element in applying tension to the ejector device. Thus a movement to release the safety cap means is associated with applying tension to the ejector device. In particular, the pricking element is then retracted in the direction opposite the direction of pricking.

[00058] According to another inventive idea, the holding body for the pricking element not only has a holding function for the pricking element but also has a guidance function in the execution of the ejection process. The outside shape of the

holding body is complementary to that of the guide means, e.g., in the form of guide walls for slidingly displaceable arrangement of the pricking element.

[00059] In another embodiment of the holding body, it has at least one position securing means, in particular in the form of a protruding web. Such a protruding web may keep the holding body and thus the pricking element in a position in the plane, for example, i.e., it may prevent rotation about the longitudinal axis of the pricking element, in particular during the ejection process, or the pricking element may slide out of the support when replacing a pricking element support.

[00060] However, a particular holding body may also have a web that is elastically spreadable in the pricking procedure and can thus exert a retraction force on the pricking element, so that the holding body together with the pricking element is retracted again behind a contact face on the housing body.

For the execution of the pricking procedure, it would be conceivable for [00061] the pricking device to have an ejector element which is under spring tension and strikes one end of the holding body and/or the respective pricking element in the pricking direction and moves it suddenly in the pricking direction. On the other hand, it has proven advantageous if the respective holding body has engagement means that cooperate with the pricking device. By means of these engagement means, a particular holding body can be coupled to the pricking device and in particular can be moved into an activated position with the tension applied to the pricking device. In this way, as mentioned above, the safety cap means can be released from the pricking element to release the safety cap means in this way, it is necessary for the safety cap means to strike against a stop means or to be otherwise held back. In an advantageous manner, the respective safety cap means is held in a form-fitting manner with respect to the support in the longitudinal direction of the pricking element so that it does not participate in this regard in a movement of the holding body together with the pricking element but instead is released from the holding body and the pricking element.

[00062] It has also proven advantageous if the safety cap means is movable across the path of movement of the pricking element in a force-guided manner. This

may be accomplished expediently by a complementary design of the support or components on the support and the safety cap means. It is pointed out explicitly that a concrete design of the safety cap means is not necessary for this purpose but instead there must always be a complementary design of the outside contour of the safety cap means and suitable receptacles, preferably in or on the support, so that immediately after the safety cap means is released from the pricking element and/or from the holding body of the pricking element, the safety cap means can be moved along this forced guidance out of the path of movement of the pricking element by means of the displacement element inside the device.

[00063] To move the safety cap means reliably and rapidly, in particular out of the path of movement, it is preferably under an initial tension, in particular across the path of movement of the pricking element. The displacement element is advantageously directly or indirectly under a prestress against the safety cap means. To avoid a relative movement between the safety cap means and the displacement element, it has proven advantageous that a displacement element is permanently assigned to each safety cap means, i.e., even outside of the respective working physician.

lt should also be pointed out that for the design of the displacement element, no obligatory requirements need be made except that after displacement of the released safety cap means the path of movement for the pricking element must be released again. In particular in this regard, it has proven to be advantageous if the displacement element has a U-shaped strap in particular which moves the safety cap means out of the path of movement of the pricking element. Due to the strap-like design, the displacement element may continue to apply a load against the safety cap means even after the displacement operation so that the pricking element can move between the legs of the strap.

[00065] It has proven to be especially advantageous that the support has disposal positions for a respective safety cap means such that the particular safety cap means can be accommodated in a manner in which it cannot be lost after being separated from the pricking element. It has proven to be especially advantageous that receptacle

positions defined in this way, in particular receptacle cavities, are provided on the support and that the safety cap means can be removed from the housing body together with the support.

[00066] According to another inventive idea, the particular safety cap means is accommodated in a clamped position in its disposal position so that it is accommodated there without causing any interfering noises. For example, it may be held under pretension of load against a wall of the support. It has proven to be particularly advantageous if the displacement element can be used for this purpose. To this end, it is advantageously designed such that it is in surface contact with the safety cap means, at least in the disposal position.

[00067] With regard to a compact design of the device, it has proven advantageous that the safety cap means is under pretension on the free end of the pricking element in its starting position, and in its disposal position, it is under pretension by the same means in particular and preferably by the displacement element.

[00068] The displacement element is preferably mounted on the support so that it can be inserted with the support into the housing body.

[00069] In a preferred embodiment of this inventive idea, the displacement element is provided on the support in such a way that it holds the pricking element with their holding bodies and the safety cap means reliably so that they cannot be lost but at the lost time so that they are slidingly displaceable on the support. In such a case it has proven advantageous if the displacement element is designed as a spring element which is in contact with the safety cap means under a load. With a rotatable design of the support for the pricking elements, the displacement element may be designed as a spring ring having spring tongues protruding radially.

[00070] Preferred embodiments of the ejector device are explained below. The ejector device may be a plunger means that can be put under tension or a ram means as an ejector element for executing the pricking operation. Although it is conceivable for

the ejector element to strike the free end of the holding body or the pricking element to accelerate it suddenly, it has proven advantageous if an ejector element of the ejector device is already connected to the holding body even before the execution of the ejection process. For this reason, the ejector element has a coupling area which can be coupled to the holding body for the pricking element so that the ejector element and the pricking element are in entraining connection even before the execution of the ejection process, i.e., the ejector element together with the holding body can execute a tension movement.

[00071] The form-fitting connection between the ejector element and the holding body and/or the pricking element can be achieved through any desired clamping means, catch straps or similar detachable connections. However, in another embodiment of this invention, the coupling area of the ejector element and the holding body can be coupled in such a way that the two can be moved in relation to one another across the pricking direction into a form-fitting entrainment connection. In such a case it is not necessary to use any flexible claws, catch means or clamping means. In particular in the case of a concentric rotatable arrangement with radially aligned pricking elements, the holding body and the coupling area of the ejector element can be rotated into the entrainment connection in the peripheral direction of the rotatable arrangement.

[00072] To apply tension to the ejector element of the ejector device against a tension force, the ejector element has a tension cam which protrudes across the pricking direction. Again, any design of the ejector device would be conceivable for applying tension to the ejector element, but the tension cam described has proven to be advantageous inasmuch as it allows a displacement of the tension mechanism for the ejector element into a parallel plane. The tension cam may then be guided in an advantageous manner along a curved path of an adjustable or operable tension means. During this movement of the tension cam along the curved path, the ejector element which is force guided in a linear path is brought into an activated state in which it is under tension. The above mentioned curved path may advantageously be a cam path or a cam guidance path of essentially any desired implementation.

[00073] It has also proven advantageous that after executing the movement in the tension direction, the tension means can be moved back under the control of a spring force. This may be, for example, a lever which is disk-shaped in particular and is mounted so that it can be pivoted or rotated, applying tension to a recoil spring with its movement in the tension direction. For example the tension means may include a lever which protrudes above the housing of the pricking device and can be deflected manually in the tension direction and returns automatically to the starting position when released again.

In an embodiment of this invention which is especially important, the tension means for applying tension to or activating the ejector device is also an adjusting means to bring a particular pricking element into a working position and to bring a used pricking element into a disposal position. Thus in particular the support with the pricking elements may be advanced by one step, in particular by rotating it further. Instead of advancing the support, it would also be conceivable to advance the ejector device in relation to the support. According to the inventive idea explained above, one adjusting movement causes the ejector device to be activated and a new, as yet unused pricking element to be brought into the working position and/or the ejector device to be brought into the working position.

arranged in such a way that in a first phase of the movement, it is in a driving connection with the support for the pricking elements and in a second phase of the movement it is in a driving connection with the ejector element. In such a case the driving connection between the tension means and the support may be released at the end of the first movement phase by having the tension means or an arm of the tension means slide up against a ramp means. In this way it is possible to achieve the effect that despite operation by the same tension means, a new pricking element is brought into the working position first in the first phase by restoring the support and in particular is coupled to the ejector element and then in the second phase of the movement, the

ejector element is moved in the tension direction, in particular together with the pricking element coupled to it.

[00076] It has already been pointed out that the prinking device may contain additional components and in particular together with a plurality of test means, an analyzer device and a display device, it may form a blood analyzer which can be handled as a single device, also known as an all-in-one device.

[00077] In such a case it has proven advantageous that the test means can also be brought one after the other into a working position in which the required minimal amount of blood can be applied to the particular test means from a previously pricked skin surface of a user. The test means may be for example membranes with test reagents contained in them with the help of which the analysis is performed optically or electrochemically or electrophysically in a known way which therefore need not be described in greater detail here. For example, in this way an analyte such as fructosamine, lactate, cholesterol or in particular glucose can be qualitatively and preferably also quantitatively determined in the minimal amount of blood just sampled.

[00078] According to a preferred embodiment of this invention, the pricking elements and/or the test means are arranged concentrically with a point of rotation so that their respective working positions are rotatable. Therefore, a first support for the pricking elements and a separate second support for the test means are advantageously provided. However, these supports may also be combined to form one unit so that they can be inserted into the device and removed from the device as one easy-to-manage unit.

[00079] With respect to extensive miniaturization of the device, it has proven to be especially advantageous if the pricking elements have a recessed circular segment with a radial arrangement on the support so that the support can be inserted into the housing body in such a way that the ejector device extends into this circular segment. Therefore due to the fact that no pricking element is provided in pie-shaped circular segment which may encompass in particular 10° to 20° in the circumferential direction, the ejector device may extend into the circular segment in the radial direction in this

area. Therefore the insertion of the support with the pricking elements and optionally also with the test means into the housing body is not prevented by the ejector device. This also proves to be advantageous when—as described above—a particular pricking element and/or a holding body for a particular pricking element and an ejector element of the ejector device are rotated in relation to one another into a coupling connection.

[00080] Additional details, features and advantages of this invention are derived from the patent claims and the attached drawings and the following description of a preferred embodiment of this invention. It should be pointed out that each feature claimed in the patent claims is considered essential to this invention, regardless of how the features are combined and regardless of their reference back to the claims, so that patent protection is also claimed for specific embodiments of the blood analyzer or the pricking elements, the support(s), the ejector device, the driving mechanism and adjusting mechanism for the pricking elements, regardless of the design of other components, in particular regardless of the design currently claimed for the blood analyzer according to Claim 1.

## In the drawings:

[00081] Figure 1 shows a perspective view of an inventive blood analyzer;

[00082] Figure 2 shows a top view of the device according to Figure 1;

[00083] Figure 3 shows an exploded diagram of an open housing body of the blood analyzer according to the Figure 1;

[00084] Figure 4 shows an exploded diagram of a support with pricking elements and test means of the device according to Figure 3;

[00085] Figure 5 shows a sectional view with a sectional plane indicated by the arrow A-A;

[00086] Figure 6 shows a sectional view with a sectional plane indicated by the arrow B-B;

[00087] Figure 7 shows a top view of the device according to Figure 1 with a different type of display;

[00088] Figures 8, 9 show another embodiment of the arrangement of pricking elements;

[00089] Figures 10-13 show another embodiment of the arrangement of pricking elements;

[00090] Figure 14 shows an example of a driving mechanism for the arrangement in Figures 10-13;

[00091] Figures 15, 16 show another embodiment of the arrangement of pricking elements with safety cap means;

[00092] Figure 17 shows the removal of the safety cap means from the pricking elements;

[00093] Figure 18 shows an activation and releasing procedure for the blood sampling device;

[00094] Figures 19-21 shows an exploded diagram and a view from above and below of another embodiment of an arrangement of pricking elements;

[00095] Figures 22-28 show an operation cycle of the blood sampling device using the arrangement of pricking elements according to Figures 19-21; and

[00096] Figure 29 shows another embodiment of the blood analyzer;

[00097] Figures 30-32 shows an operating cycle of the blood sampling device in the embodiment according to Figure 29;

[00098] Figure 33 shows a perspective view of a preferred embodiment of an inventive pricking device;

[00099] Figure 34 shows a perspective view into the interior of the pricking device according to Figure 33 with the cover part omitted;

[000100] Figures 35 and 36 show and exploded diagram of components illustrated in a housing body of the pricking device according to Figures 33 and 34;

[000101] Figures 37 and 38 show a pricking element of the inventive pricking device;

[000102] Figures 39a through c show the production process for a pricking element;

[000103] Figure 40 shows a perspective view of a support for the pricking elements;

**[000104]** Figure 41 shows a perspective view of a holding means for the pricking elements on the support which at the same time forms a displacement means for the safety cap means;

[000105] Figures 42, 43 show a perspective view of the support with pricking elements before and after use;

[000106] Figures 44 and 45 show a perspective view of the housing body of the pricking device;

[000107] Figure 46 shows a perspective view of the ejector element of the pricking device;

[000108] Figure 47 shows a perspective view of the triggering means of the pricking device;

[000109] Figure 48 shows a perspective view of the tension means of the pricking device and

**[000110]** Figure 49 shows a view of the pricking device from beneath with the lower covering part omitted.

[000111] Figures 1 and 2 show a perspective view and a top view of an inventive blood analyzer which is labeled on the whole with reference number 2. The blood analyzer is designed as a so-called complete device and includes a housing body 4, to be explained in greater detail below, which accommodates a blood sampling device 6 having a plurality of pricking elements 8 and a plurality of test means 10. Unused

pricking elements 8 and test means 10 are stored in magazines in the housing body 4 and are removed after use, whereupon they are discarded and/or disposed of. The blood analyzer 2 also includes an analysis device 12, which is only indicated here and has an electronic analyzer (not shown) and a display device 14 in the form of a visually readable display for displaying the results of an analysis, i.e., in particular displaying the amount of an analyte, in particular the blood sugar content.

**[000112]** The housing body 4 of the blood analyzer 2 according to this invention is designed in a circular disk shape in the manner of the casing of a wristwatch. It also includes opposing fastening means 16 in the form of two aligned openings 18 to receive a strap of an essentially conventional wristwatch band.

[000113] A pricking position 22 is formed on a wall 20 of the housing body 4 which is in the shape of a cylindrical section for coming in contact with a skin surface, in particular of a user's finger. The pricking position 22 is formed by a sliding part 24 which is movable in the circumferential direction with respect to the wall 20 and has a through-opening 26 in the form of an elongated hole extending in the circumferential direction such that a pricking element 8 can be pushed through the opening so that the skin surface of the user can be pricked to obtain a minimal amount of blood. By adjusting the sliding part 22 [sic; 24 above] in the circumferential direction, the depth of penetration of the pricking element 8 can be adjusted. The pricking element 8 in Figure 1 is depicted in its maximally ejected forward position, which the pricking element assumes only for an extremely brief period of time during the execution of the pricking operation. When the blood sampling device 6 is not in operation, the pricking element 8 is inside the housing body 4.

[000114] As shown by Figures 1 and 2, a segment 28 of the housing body 4 having a convex shape as seen from above can be partially moved out of the housing body 4 so that the segment 28 exposes a charging position 30 which is oriented axially with respect to the plane of the disk-shape housing body 4. In this charging position 30 a minimal amount of blood is charged to a test means 10 which is situated directly beneath this charging position. When the test means 10 is in the position shown in

Figures 1 and 3, where it is associated with the charging position 30 on the housing body 4, the test means being wettable with a minimal amount of blood in this position, then it is by definition in its working position. Similarly, the pricking element 8 shown in Figures 1 and 3 is in its working position which is provided for the pricking position 22 in which it can prick the skin surface of a user in a manner to be described in greater detail below.

[000115] The segment 28 is held displaceably along a convexly curved side 36 facing inward by means of a sliding guide rail 38 with an engagement place on the remaining housing body 4. When the blood analyzer is not in use, this segment can cover the charging position 30 so that its other convexly curved side 42 which is provided with a grooved gripping surface 40 forms a part of the cylindrical outside 20 of the housing body 4.

When a blood analysis is to be performed, the user slides the segment 28 [000116] into the position illustrated in Figure 1 so that the charging position 30 is exposed. At the same time, this movement activates the blood sampling device 6 which is provided in the interior of the housing body 4 by applying tension to an ejector mechanism 44 which can be seen in Figure 3 by mechanically applying tension to a spring. The user can then place a finger against the pricking position 22 and trigger the blood sampling device 6 by operating a button 46. Then a ram 48 of the ejector mechanism 44 is pushed radially outward by the spring force as the spring is released. The ram 48 then pushes the pricking element 6, which is in its working position 34, outward in the radial direction so that it pricks the skin surface of a user through the through-opening 26. The user then removes his finger from the pricking position 22, allows a minimal amount of blood to escape from his finger and then places his finger in the charging position 30, thereby transferring a minimal amount of blood to the test means 10 which is in its working position 32. Then the analysis of the analyte begins and the result is displayed by the display device.

[000117] Figures 4 through 6 give an example of an illustration of the arrangement of the pricking elements 8 and the test means 10 as well as the blood sampling device

6 with its ejector mechanism 44 in the interior of the housing body 4. Figure 4 shows a perspective view of a support (labeled with reference number 50 on the hole) for the pricking elements 8 and test means 10, whereby the support 50 forms a type of magazine-like receptacle for pricking elements 8 and test means 10 and can be inserted as manually handleable unit into the device and can be removed again after use and disposed of as a whole together with the used pricking elements and test means.

[000118] The support 50 as a fist support part 52 in the form of an essentially planar ring disk 54 for the test means 10 and a second support part 56 in the form of a strip 58 which is curved into a circular shape and has pricking elements 8 held on it, arranged in radial direction.

[000119] The second support part 56 is placed on another ring disk-shaped support part 60 the plane of which extends parallel to the first support part 52. The second support part 56 and this additional support part 60 are coupled together in a rotationally fixed manner by recesses 62 on a part and intermeshing projections 64 on the other part. The recesses 62 and the projections 64 may also cooperate in a frictionally engaged manner so that the second support part 56 is permanently joined to the additional support part 60. The first support part 52 can be clipped in a similar manner onto the second support part 56 by the fact that form-fitting and/or preferably clamping recesses 62 and projections 66 between these two parts work together cooperatively.

[000120] The test means 10 are arranged in concentric recesses 68 provided on the first support part which are punched recesses or punched holes. They are arranged in such a way that they are accessible in the axial direction, i.e., in the direction of an axis of rotation 70 of the support 50. In the case of each test means 10, contacts 69 are indicated on the top side of the first support part 52, such that an electrode array (not shown) of the test means can be contacted and can be connected to the electronic analyzer. Thus in the present case, electrochemical test means are used; such means are adequately well known and therefore need not be described in greater detail here.

[000121] The radially arranged pricking elements 8 on the second support part 56 each pass through a spring element 74 which can be put under tension in the radial direction. The pricking elements 8 have a thickened head 76 on the inside radially which cannot move due to the spring 74. In ejection of the spring element 74 in the radial direction, the spring element 74 is therefore put under tension, therefore causing a radial retraction of the spring element 74 essentially into the position shown in Figure 4 within the housing body 4. The spring elements 74 therefore form retraction means 78 for the pricking elements 8.

[000122] The three support parts 52, 56 and 60 are designed in the form of a ring and have a central recess 80 in which the ejector mechanism 44 is accommodated, as shown in Figure 3. The additional support part 60 comprises internal gearing 82 which cooperates with a driving wheel 84 (see Figure 3). The driving wheel 84 is drivable by an electric motor or by other means, e.g., by operating slide or by rotation of a manually operated wheel on the housing of the blood analyzer. The support 50 is rotatably mounted on a central housing projection 85 which engages in the recess 80 as shown in Figure 3. A planar axial surface 87 here forms an axial bearing surface against which the surface areas of the additional support part 60 which are directly connected to the internal gearing 82 are in sliding contact.

[000123] In the sectional view according to Figure 5, the plane of intersection passes through the working position 32 of the test means 10. A pricking element 8 can also be seen in the sectional view but it is not in the working position for pricking elements. The working position for pricking elements is included in the sectional plane according to Figure 6, where the pricking element 8 is shown in the maximally ejected position. The ejector mechanism 44 shown in Figure 3 is not shown in the sectional view according to Figure 6. Figures 3, 5 and 6 show how the support 50 can be inserted together with the pricking elements 8 and the test means 10 in the form of a cassette into the interior of the housing body 4 of the blood analyzer. The housing body 4 is bordered at the bottom by a covering part 86 and at the top by a wall 88 which runs

across the axis of rotation 70. Above this wall 88 another room 90 is provided for the analyzer device 12 and its electronic components.

[000124] Figure 7 shows a stop view of a blood analyzer corresponding to that in Figure 2; this blood analyzer differs from the one described above in that a time display device 92 in the form of a conventional watch face is provided on the visible side of the housing body 4. However, this time display can also be in the form of an LCD display according to Figure 2. In such a case, one could preferably select between a time display and an operating mode which displays the result of the blood analysis.

explained below. In a perspective view, Figure 8 shows an arrangement of pricking elements within sleeve means 100 which are arranged radially and on a strip 102 which is curved into a closed circular shape as the support part 104. Plunger means 106 extend from radially inward into the sleeve means 100, with the sleeve means 100 forming a cylindrical receptacle. The plunger means 106 carry the pricking elements (not shown in Figure 8) which are then accommodated within the sleeve means 100 in the radial direction. Two spring tongues 108 in the form of webs included toward the radial direction are provided on the inside end radially of the plunger means 106. When a particular plunger means 106 is pushed radially outward in the direction of the arrow 110, the spring tongues 108 become deformed and exert a retraction force on the respective plunger means 106 so that the latter is retracted at least slightly.

**[000126]** The sleeve means 100 have a cover 112 in the form of a film section on the outside radially such that the pricking element can either puncture through the film section or the film is partially or entirely removed immediately before executing the operation.

[000127] Figure 9 shows an enlarged detail from Figure 8. The plunger means 106 with the pricking element 114 incorporated into it during the injection molding operation can be seen here. Between the inside cylindrical wall 116 of the sleeve means 100 and the plunger means 106, a sealing means is provided in the form of a ring bulge 118 on the wall 116 and a ring bulge 120 on the plunger means 106. When the plunger means

106 is ejected radially in the direction of the arrow 100, the ring bulge 120 slides over the ring bulge 118 under the influence of the cylinder wall 116. Before executing the pushing operating, the two ring bulges 118 and 120 form a seal for the cylinder space, so that the pricking element 114 is accommodated under sterile and sealed conditions. On the other side, the cylinder space is sealed by the film 112.

**[000128]** Figure 10 shows another embodiment in which the pricking 122 are accommodated in hemispherical wells 124 in a disk-shaped support part 126 and extend in the axial direction, i.e., parallel to the axis of rotation 70 of the support part 126.

**[000129]** Figures 11 and 12 show two perspective views of the support part 126 according to Figure 10. Gear teeth 130 for rotating drive of the support part 126 can be seen on the bottom side 128. Instead of the gear teeth, however, a recess with internal gearing may also be provided.

[000130] As shown by the detailed diagram in Figure 13, the pricking elements 122 are injected into trunk-shaped support sections 132 which are designed in one piece with the material of the hemispherical walls 133 which border the wells 124. The wells 124 are covered with a film 134 at the top, then forming an airtight sealed space to receive the respective pricking element 122. In addition, ring-shaped weakening grooves 136 can be seen in the edge of the support part 126 bordering the wells 124.

[000131] Figure 14 illustrates the drive mechanism for the blood sampling device in the axial arrangement of the pricking 122. For example, it is possible to use a pushing mechanism which acts radially with a radially movable pushing element 138, whereby the radial movement via a wedge-shaped slope 140 can be used for axial deflection of the pricking elements 122. The slope 140 slides with respect to the trunk-shaped support section 132 which holds the pricking element 122 and deflects it in the axial direction, causing deformation of the trough shape, as depicted in four different stages in Figure 14.

[000132] Figures 15 and 16 show perspective and exploded diagrams, respective of another arrangement of the pricking elements 140 as part of the blood sampling device on a rotating support part 142. The pricking elements 140 are in turn arranged in a radial alignment and are injected with one end in a holding ram 144 made of plastic. As with the plunger means according to Figure 8, spring tongues 146 are integrally molded on the holding ram 144 and apply tension to the holding ram 144 and thus the pricking elements 140 with a radial movement, then causing the pricking elements to be retracted. The support part 142 has bearing projections that are integrally molded in one piece for accommodating and for radially displaceable support of the holding rams 144 with the pricking elements 140. The pricking elements 140 injected into the holding rams 144 are preferably completely surrounded by a safety cap means 147 which forms a sterile environment and thus a sterility barrier for the pricking elements 140.

A spring ring 148 is preferably undetachably connected to the support 142 [000133] from above by essentially any known joining means such that the holding rams 144 are movable in the radial direction but are held so they cannot be lost. A web 150 of the spring ring 148 arranged above a respective safety cap means 147 exerts a slight pressure in the axial direction on the safety cap means 147. The ejector mechanism of the blood sampling device is designed in the present case so that immediately before execution of a pushing, i.e. pricking operation, the holding ram 144 which is in the working position is pulled slightly toward the inside radially. In doing so, the safety cap means 147 is initially held in its position by stop means so that the respective pricking element 140 is released from the safety cap means 147. The safety cap means is then moved into a recess 152 in the support part 144 under the action of the resilient web 150 so that the safety cap means is brought out of the path of movement of the pricking element 140. This process of retracting the holding ram 144, releasing the safety cap means 147 and bringing the safety cap means out of the path of movement of the pricking element is depicted in Figure 17.

[000134] Figure 18 shows schematically the activation of the blood sampling device. On the whole an ejector mechanism is reference number 48 comprising a ram-

like ejector element 154 which can be ejected in the radial direction and retracted again by means of a tension and compression spring 156. The ejector mechanism 44 can be put under tension by means of a rotatable adjusting means 158 with a radially protruding cam 160 by the fact that due to cooperation of the cam 160 with a projection 161 on the ejector element 154, the ejector element can be moved against the compressive force of the spring 156 so that it is held in an activated state by a catch mechanism 162 while retaining the spring tension. The adjusting means 158 with the cam 160 is spring-loaded to move it back into its starting position in particular. Then when the catch is released manually, the ejector element 154 snaps back suddenly in the radial direction under the influence of the spring force, whereby the free end of the ejector element 154 strikes the end of the pricking element or a holder carrying the pricking element and also pushes it the outside. Then the ejector element 154 is again moved into its starting position (shown in Figure 18) by means of the spring 156. The pricking element is then retracted back into the housing under the influence of the spring means described above.

**[000135]** Figures 19 through 29 illustrate another preferred embodiment of the arrangement of pricking elements on a rotating support.

**[000136]** Figure 19 shows an exploded diagram of a pricking element cassette which is shown in the assembled condition from above in Figure 20 and beneath in Figure 21.

[000137] It includes a support part with holding rams 172 that are arranged so they can move radially and have pricking elements each of which is covered by a safety cap means 174, the arrangement here largely corresponding to that according to Figure 15. It also has a ring-shaped spring means 176 which cooperates with each safety cap means 174 as described in conjunction with Figure 17. The components described above can be used in another support part 178 with a cylindrical wall area 180 pulled upward. This additional support part 178 has a receptacle 182 that forms a housing and protrudes into the interior for a ram-like or plunger-like ejector element 184 which can be moved radially in the support part. A first driving spring 188 is provided between one

end 186 of the ejector element 184 on the inside radially and a wall of the receptacle 82 which forms the housing. A restoring spring 192 is provided between a ring collar 190 of the ejector element 184 and the receptacle 182.

[000138] The ejector element 184 also has on its circumference a holding means 194, e.g., in the form of a ring groove by means of which the ejector element 184 can be held in the receptacle 182 when tension is applied to the spring 188. This can be accomplished by a catch mechanism, which is formed in the present example by a clamping spring 196 and cooperates with the holding means. The ejector element 184 has an engagement means 198 on its outer end radially to retract the holding ram 172 in order to release the safety cap means 174. The engagement means engages behind an engageable section 200 of the holding ram 172. This engageable section may be formed by a thickened end 201 which is therefore also designed to accommodate a pushing force and is on the holding ram 172.

[000139] A control lever 202 which is designed to cover an area and can rotate about the axis of rotation 70 of the support part 170 is provided on the outside of the support part 178. The control lever 202 comprises a cam control surface 204 which cooperates with a cam means 206 of the ejector element 184 which extends in the axial direction through a recess 208 in the bottom of the support part 178. When the control lever 202 in Figure 21 is pivoted clockwise, the cam control surface 204 comes into operative contact with the cam 206 and forces the cam 206 and with it the ejector element 104 inward in the radial direction with further rotation of the control lever 202 so that the driving spring 188 is put under tension. The ejector element 104 can be locked in the condition of the spring 188 in which it is under tension by means of the holding mechanism or catch mechanism described above as an example, even when the control lever 202 is rotated back into the starting position shown in Figure 21.

[000140] In addition, the control lever 202 has an entraining means 210 in the form of a catch lever 212 which is elastic in the axial direction and by means of which the support part 170 and thus the arrangement of the pricking elements can be rotated in the circumferential direction. To this end, the catch lever 212 engages through a recess

214 which extends in the peripheral direction in the bottom of the support part 178 and grips the support part 170. Therefore the support part advantageously has a crown catch arrangement 216 which is merely indicated in Figure 21.

[000141] When the control lever 202 is rotated starting from the position illustrated in Figure 21, the catch lever 212 causes the support part 170 to continue rotating so that a new pricking element that has yet been used is brought into its working position. In doing so, the respective holding ram 172 with its engageable section 200 slips into the engaged situation with the engagement means 198 of the ejector element 184 as shown in Figure 20. To simplify this positioning movement, it has proven to be especially advantageous if the engagement means 198 is provided with a sloping approach or an insertion slope 218 as shown in Figure 20 or Figure 19. Positioning inaccuracies in the resting state of the ejector element 184 can be compensated by means of this slope 218 which is preferably designed on the inside radially and on the outside radially.

To ensure that a particular pricking element is positioned exactly in the [000142] working position of the pricking elements and its not transported further inadvertently, a transport interruption device 220 is provided exactly in this rotational position. This transport interruption device 220 is designed for example and in an advantageous manner so that it causes an axial deflection of the catch lever 212 so that its entrainment means 210 can no longer cooperate with the crown catch arrangement 216. Therefore, the catch lever 212 includes a radial projection 222 which slides toward an outside of the support part 178. This outside of the support part 178 has a slope 224 at an appropriate location which raise the catch lever in the axial direction in the sense described above when the control lever 202 reaches this slope 224 in its rotation. When the control lever 202 is rotated back, the entrainment means 210 of the catch lever 212 slides over the oblique flanks of the crown catch arrangement without causing the support part 170 to rotate back however. To reliable prevent the support part 170 from turning backwards, a reverse rotation prevention device 226 is divided, this device being implemented in an advantageous manner through a suitably oriented crown catch gearing 228 on the inside of the support part 178, as illustrated for example in Figure 19. The design and orientation of this crown catch arrangement 228 are such that it cooperates with the crown catch arrangement 216 of the second support part 170 so that the support part 170 can be rotated in the direction of conveyance but not in the opposite direction. A slight axial deflectability of the support part 170 with respect to the other support part 178 is necessary for this. The reverse rotation preventing device 226 could, however, also be implemented in another manner.

**[000143]** Figures 22 through 29 show an operating cycle of the arrangement of pricking elements described above. Each figure shows at the left a view of the pricking element cassette from underneath and the right side of the figure shows a view of the cassette from above.

[000144] Figure 22 shows the control lever 202 in the starting condition where it is in contact with an end stop 230. The right side of Figure 22 shows a holding ram 172 with pricking elements and safety cap means 174 emphasized in a position in front of the working position of the pricking elements.

clockwise whereby the entrainment means 210 engages in the crown catch arrangement 216 on the bottom of the support part 170 and likewise conveys, i.e., rotates the support part 170 and the pricking elements arranged thereon in the clock direction, namely until the holding ram 172 mentioned above has reached the working position, namely the position shown at the right in Figure 23. The approaching slope or insertion slope 218 described above can be seen in Figure 23 with the engagement means 197 of the ejector element.

[000146] When the control lever is turned further according to Figure 24, the radial projection 222 and thus the catch lever 212 are deflected axially by sliding up against the slope 224 in the axial direction, so that the support part 170 cannot be rotated further. At the same time, the cam guidance face 204 of the control lever 202 presses the cam 206 and thus the ejector element 184 radially inward, putting tension on the ejector spring 188. Through the cooperation of the engagement means 198 and the

engageable section 200 of the holding ram 172, the latter is entrained radially inward, so that for the first time the pricking element 232 which can be seen at the right in Figure 24 is released from the safety cap means 174.

[000147] Figure 25 shows the maximally rotated state of the control lever 202 and/or the ejector element 184 in that the ejector element 184 has been locked in the taut position via a holding mechanism which is formed mainly by the clamping spring 196 and the ring groove on the ejector element 184. When the control lever 202 is pushed back according to Figure 26, the ejector element 184 therefore remains in its taut position. The safety cap means 174 is now brought by the axially acting spring means 176 out of the path of movement of the pricking element 232.

[000148] Finally, Figure 27 shows the pricking operation that is performed, whereby the ejector element 184 is snapped outward in the radial direction by operating the holding means in the form of spreading of the clamping spring 196, so that the ejector element strikes the end of the holding ram 172, pushing it outward together with the pricking 232.

**[000149]** At the next moment, the restoring spring 192 causes a retracting movement of the ejector element 184 into the starting position shown in Figure 28 in which the pricking element in the working position has been retracted into the housing.

[000150] Figures 29 through 32 illustrate a preferred embodiment of the driving device, i.e., the ejector mechanism for a pricking element which is in its working position, these figures illustrate (independently of the arrangement and the design of the pricking elements on a rotating support) the activation, i.e., tensioning of the driving device for the pricking elements and further rotation of the support by means of a single control element 238 which is formed in an exemplary manner by the covering part mentioned previously. Details in this regard are given below.

**[000151]** Figure 29 shows a perspective view of the support component of this embodiment of the analyzer, omitting the components that form the housing. However, the covering part 28 has an arrangement of teeth 240 like a toothed rack the inside 36

in combination with the sliding guide rail 38 illustrated in Figure 2 on its inside 36. These teeth 240 can be brought into engagement with the teeth of a first gear wheel 242 which can be rotated in the plane of movement of the covering part 28. This first gear wheel 242 is arranged in a rotationally fixed manner on a shaft 244 which extends perpendicular to said plane and as on its other end a second gear wheel 246 on the output end. This second gear wheel 246 can be brought into and out of engagement with internal gearing 82 on a support part 60 (the same reference notation as that used in Figures 1 though 6 has also been used here). The shaft 244 is movable in an elongated hole 248 which extends in said plane of movement. When the covering element 28 is pivoted in the direction of exposure of the charging position mentioned in conjunction with Figure 1, the shaft 244 is forced into the position shown in Figure 29 at one end of the elongated hole 248 where the second gear wheel 246 meshes with the internal gearing 82 of the support part 60 so that the support part 60 and thus the arrangement of pricking elements are rotated further in the clockwise direction with rotation of the gear wheel and shaft arrangement. When the covering part 28 is pushed or pivoted back into its starting position, the gear wheel and shaft arrangement is forced toward the opposite end of the elongated hole 48, so that the teeth of the second gear wheel 246 are disengaged with the internal gearing 82 of the support part 60. This prevents the arrangement of pricking elements 8 from rotating backwards.

[000152] The driving device for a pricking element which is in the working position shall be referred to on the whole with reference number 250 and comprises an ejector mechanism 44 with a ram 48 which acts on the respective pricking element. The driving device 250, however, also includes a tension mechanism which is formed in the present case by the first gear wheel 246 and a bending spring 252, and has a triggering device 254 comprising a lever arrangement 256.

[000153] The bending spring 252 is attached at one end on a bending spring receptacle 258 on the second gear wheel 246 and at the other hand on a bending spring receptacle 260 on a component 262 which can be swiveled with respect to the housing body 4. This swivelable component 262 is part of the lever arrangement 256

which connects this component 262 to a pushbutton 264 in the pricking position 22 on the housing body 4.

In the outward movement of the covering part 28, the second gear wheel [000154] 246 does not rotate just the support part 60 further, but instead swivels the bending spring receptacle 258 and thereby puts the bending spring 252 in a taut state. By operating the pushbutton 264, the other bending spring receptacle 260 is also pivoted by the lever arrangement 56 so that the bending spring 252 is suddenly relaxed from its stable taut state in which it is under tension beyond a dead point, thereby causing the ram 48 to be pushed radially outward and this in turn causes the respective element to execute the pricking operation also by pushing it radially outward. This movement sequence is illustrated in Figures 30, 31 and 32. These figures each show a view from above and below the components that are of interest here within the housing body. Figure 30 shows the driving device 250 of the blood sampling device in an unactivated starting state. The bending spring 252 assumes a curved shape between the bending spring receptacles 258 and 260. When the covering part 28 is swiveled in the direction of exposing the charging position 30, as shown in Figure 31, the support part 30 is also rotated via the gear wheel 242, the shaft 244 and the gear wheel 248 as well as the internal gearing 82. At the same time the bending spring receptacle 258 on the second gear wheel 246 moves counterclockwise in the diagram in Figure 31a and the bending spring 252 assumes an S-shape curve. Meanwhile, the bending spring receptacle 260 and the position of the pivotable component 262 remain unchanged. The driving device 250 and its bending spring 252 are now in a taut activated state. When a user activates the triggering device 254 by depressing the pushbutton 264 to trigger the pricking process, the pivotable component 262 is pivoted into the position illustrated in Figure 32a via the lever arrangement 256. This causes the bending spring 252 to move over a dead point position and the spring energy stored in the spring which when it is under tension in an S shape is released suddenly when the spring assumes the curved shape again shown in Figure 32a but with the opposite curvature from that in 29a. By coupling the bending spring 252 to the ram 48 of the ejector mechanism 244, the latter is also pushed outward suddenly,

[000155] When minimal amounts of blood for applying to a test means of the blood analyzer were mentioned above, this was understood to refer to quantities of blood of <20  $\mu$ L, in particular <10  $\mu$ L and preferably <5  $\mu$ L.

[000156] Figures 33 and 34 show perspective views of a pricking device label on the whole with reference 2' for taking a sample of a minimal amount of blood from the human or animal body for analytical purposes. A covering part 4' which is shown in Figure 33 and is hinge connected and swivelable has been omitted in Figure 34. In the interior of the housing body 6' can be seen a plurality of pricking elements 8' which are arranged concentrically and radially and will be described in greater detail below. At the center of the concentric arrangement can be seen an ejector device 10' which defines a pushing direction or pricking direction 12'.

[000157] Figures 35 and 36 show exploded diagrams illustrating the components that can be inserted into the housing body 6'. It can be seen here that the pricking elements 8' which are provided with a protective sheathing and are to be described in greater detail below (their radial arrangement is shown in Figure 35) are slidably displaceable in the radial direction on a support 14' in the form of a ring disk in guide paths or guide recesses 16' provided for this purpose in the support 14'.

[000158] Above the pricking elements 8', a ring disk 18' made of spring steel can be seen in Figure 35, holding the pricking 8' in a manner which is to be described in greater detail below in the guide recesses 16' of the support 8' so that they cannot fall out but they are radially displaceable.

[000159] Above the ring disk 18' there is a second support 20', illustrated with the contact 22' which is indicated schematically for the test means 24' provided in the area of the contact 22' for performing the blood analysis, i.e., for determining the presence and concentration of an analyte, e.g., blood sugar, lactate, cholesterol or fructosamine. It would be conceivable for these membrane-like test means 24' which are not shown in detail but are in particular like a membrane to be acted upon by the required minimum amount of blood through a charging opening in the cover part 4' of the pricking device. However, it would also be conceivable for an analytical test strip (not shown) to be

output through a slot-shaped opening 28' and to be wetted with a minimal amount of blood. Then an analysis can be performed by amperometer or potentiometry via the contact 22' and an analyzer device (not shown). Inclusion of separate analysis test strips would also be conceivable; these test strips could then be inserted through the slotted opening 28' to the contact 22' on the support 20' which is thus not included in the interior of the housing body 6' on the support 20'. In a preferred embodiment, however, the second support 20' carries a number of test means 24' corresponding to the number of pricking elements 8'.

**[000160]** A display device having a display screen can be mounted on the visible side of the covering part 4' which faces upward in Figure 33, e.g., in combination with the usual components of a wristwatch.

[000161] Figure 36 shows the housing body 6' which has a bottom plate 32' with an edge section 34' which protrudes upward cylindrically as well as a dome-shaped elevation 36' arranged in the center with a circular circumference 38' in some sections. A disk-shaped component 42' which is provided with an operating level 40' which protrudes radially upward is mounted so it can turn on the underside of the bottom plate 32'. It is held by a cover part 44' on the bottom side so it can rotate on the underside of the bottom plate 32' of the housing body 6'. This also shows a retraction means in the form of a recoil spring 36'. The disk-shaped component 42' forms a tension means 48' for the ejector device 10'.

[000162] In the middle of the dome-shaped elevation 36', the ejector device labeled with reference number 10' on the whole is accommodated. It includes an ejector element 50' which is to be described in greater detail below, an ejector spring 52' and a restoring spring 54', a triggering means 56' and a cover 58'. The ejector device 10' can be activated by swiveling the operating lever 40' and thus the disk-shaped component 42' by applying tension to the ejector element 50' against the pressure of the ejector spring 52'. By operating the triggering means 56', the ejector element 50' is ejected in the radial direction and executes a pricking operation together with a pricking element 8', whereupon the pricking element 8' is briefly pushed forward over the contact position

60' shown in Figures 33 and 34 and thereby pricks the skin surface by being pushed beyond the position 60' of contact with the user's finger, as shown in Figure 33 and 34, so that immediately thereafter a user can force a minimal amount of blood out of the tip of his finger.

[000163] The components mentioned briefly above will now be described in greater detail below in terms of design and function on the basis of individual diagrams:

Figure 37 shows a perspective diagram on a greatly enlarged scale of a [000164] pricking element 8' with the enveloping sleeve also shown in Figures 34 and 35. This sleeve includes a holding body 62' made of plastic which is integrally molded on the actual needle-shaped pricking element 8' (frequently also referred to as a lancet) and a safety cap means 64' in the area of the pointed end 65' (see Figure 38b). In the ejection process, the pricking element 8' is held through the free opening 66' in the holding body 62' held in the injection mold. In one operation the holding body 62' and the safety cap means 64' are integrally molded. The holding body 62' and the safety cap means 64' show a transition into a transitional area 68' which has a thin wall and forms a weakened area 70'. However, it should be pointed out explicitly that a design of these components that is not in one piece around the pricking element 8' would also be conceivable by means of sliding parts or by successive production of the holding body 62' and the safety cap means 64'. In addition, an open area 72' can also be discerned in the transitional area 68', thus promoting the development of the thin-walled weakened area 75. This open area 72' may be formed, for example, by another holding means for the pricking element 8' in the injection process.

[000165] A web 74' which has a rounded free end 76' and is formed in one piece with the holding body 62' and stands away from it can also be discerned forming an oblique angle of approximately 40° to the longitudinal direction of the pricking 8'. The web 74 is designed to be spreadable in the direction of the double arrow 78' or elastically deformable with respect to the cube-shaped holding body 62' for the element 8'. On the one hand it ensures a stabilization in the contact plane for the holding body 62' and prevent tilting about the longitudinal direction, for example. After executing a

pushing operating, however, it may also initiate a retraction torque into the holding body and thus into the pricking element 8', thereby retracting the latter again. It also secures the pricking element 8' to prevent it from sliding out of the guide recesses 16' in the support 14'.

[000166] The safety cap means 64' has an H-shaped design when seen from above. It has guide recesses 80' on both sides with which it is held on the support 14' so that it cannot be displaced in the longitudinal direction of the pricking element 8', i.e., in the radial direction, but on the other hand, it can slide laterally, namely normal to the longitudinal direction of the pricking elements 8' with respect to the support.

[000167] Figures 38a, b and c illustrate the dimensioning of the pricking element which is largely miniaturized with the holding body and the safety cap means. In its longitudinal direction it includes a length of only 12.5 mm, including the holding body 62' and the safety cap means 64'. Figures 39a, b and c illustrate the production process and separation process in the production of the pricking elements 8' which are surrounded by the holding 62' and the safety cap means 64'. It can also be seen from Figure 37 that the end of the holding body 62' which faces away from the safety cap means 64' is designed with a step and has a step 82' which exposes the pricking element 8'. By means of an upper blade 84' and a lower blade 86' which are indicated here, the pricking element 8' is cut form a continuous wire or tube by bringing the upper blade 84' almost into contact with the step 82' and thus positioning it in a defined manner with respect to the holding body 62' and the pricking element 8'. This is illustrated in Figures 39a through 39c.

[000168] Figure 40 through 43 show the arrangement of the pricking elements 8' together with the holding body 62' and the safety cap means 64' on the support 14'. The support 14' is designed in the form of a ring disk and has a complicated contour on its visible side which is shown here. In the case depicted here it comprises 10 radial recesses 16' which are bordered by a supporting wall 88' which lies in the plane of the disk and two lateral guide walls 90' which are aligned radially and perpendicularly to the former. A pricking element 8' with a holding body 62' and a safety cap means 64' is

slidingly displaceable radially therein in the guide recesses. The respective pricking elements 8' are inserted into the guide recesses 16' from above, i.e., in the axial direction and then assume the positions illustrated in Figure 34 and in Figure 42. It can be seen that no element 8' is situated in a circular segment 91' of the support 14'. When the support is inserted from above into the housing body 6', the support 14' is to be positioned in such a way that the circular segment 91' is oriented above the ejector device 10' so that the ejector device 10' extends with its outer radial end into this circular segment 91'. The ejector element 50' is then more or less arranged between two adjacent pricking elements namely the first and last pricking elements, within the circular segment 91'. A positioning means or a positioning aid in the form of an arrowshaped contouring of the ring disk 18' can also be seen. The pricking elements 18' are held in their positions within the guide recesses 16' of the support 14' by means of the ring disk 18' which is made of spring steel. To this end the ring disk 18' is pushed over a number of openings 92' onto corresponding pins 94' of the support 14' and these are then widened in the manner of a rivet, in particular by ultrasonic welding. The ring disk 18' made of spring steel has radially protruding tongues 96' which are oriented parallel to the supporting wall 88' and hold at guide a particular housing body 62' of a respective pricking element 8'. Another strap-shaped tongue 98' which is designed in a U shape extends around each tongue 96' and is connected with the two legs of the U shape to the ring disk 18'. The strap-shaped tongue forms a displacement means 99' for the safety cap means 64' to displace it out of the path of movement of the pricking element 8'. The connecting webs 100' of the tongue 98' which run in the circumferential direction are angled slightly upward in relation to the plane of the risk disk 18' and are designed in a meandering pattern. They therefore each define a contact plane which runs slightly obliquely to the plane of the ring disk 18'. This is for the following reason: it can be seen from Figure 10 that the connecting webs 100' and the plane formed by them are also arranged obliquely in relation to the top side 102' of the respective safety cap means 64'. Likewise the respective connecting web 100' rests under a slight pretension on the top side 102' of the respective safety cap means 64'. When a holding body 62' with the injecting pricking element 8' is pulled radially inward in a manner to be described in

greater detail below and the weakened area 70' between the holding body 62' and the safety cap means 64' is punctured, the strap-shaped tongue 98' with its connecting web 100' presses the respective safety cap means 64' downward across the direction of pricking or the longitudinal direction of the pricking element 8' into the position illustrated in Figure 11. In this disposal position 103', the connecting web 100' of the resilient tongue 98' rests on the surface on the top side 102' of the respective safety cap means 64' (Figure 43 shows the pricking elements 8' after execution of the pricking process).

[000169] In addition, strip-shaped guide bars 104' oriented in the axial direction and engaging in the guide recesses 80' of the respective safety cap means 64' can also be seen in Figures 40, 42 and 43. The respective safety cap means 64' is displaceable in the axial direction, i.e., perpendicular to the radially oriented pricking direction on these guide bars 104'. At the same time, these guide bars 104' hold a respective safety cap means 64' undisplaceably in the radial direction so that when the holding body 62' is pulled inward, the weakened area 70' can be broken. Then subsequently, as explained above, a respective safety cap means 64' is accommodated in a receptacle cavity 106' in the support 14' which forms the disposal position 103' for the safety cap means. In this receptacle cavity 106', a respective safety cap means is then held without play under load by the elastic tongue 98' in the form of strap. This prevents any interfering rattling noise.

[000170] Figures 44 and 45 show the

housing body 6' with and without the respective components of the ejector device 10'. It can be seen here that the dome-shaped elevation 36' in the housing body 6' forms a receptacle for the pushing element 50', the pushing spring 52' and the restoring spring 54'. These components are held by the cover 58' so they cannot fall out and yet they are longitudinally displaceable in the receptacle in the pricking direction 12', i.e., in the radial direction. Figure 14 shows in a greatly enlarged diagram the pricking element 50' which is designed in the form of a plunger means or a ram means which has an outside diameter with a shoulder and thus forms an axial step 108' against which the restoring

spring 54' is supported at one end. At the other end the restoring spring 54' is supported against a cheek 110' of the dome-shaped elevation 36'. The pushing spring 52' is supported on the end 112' which has the larger diameter, and on the other end it is supported against a cheek 112' of the dome-shaped elevation 36'. The pushing element 50' also includes a coupling area 116' which is opened in the pushing direction but also in the circumferential direction. This coupling area 116' is designed to be complementary to an engagement area 118' (see Figure 37) of the holding body 62' and is able to accommodate this area so that the holding body 62' can be coupled to the pushing element 50' and forms a form-fitting entrainment connection with the pushing element 50'. With the orientation of the pushing element 50' shown in Figure 45, a holding body 62' of a pricking element 8' can be rotated into this coupling area 116' by rotating the support 14', as illustrated in Figure 2. If the pushing element 50' is retracted radially inward when it is in entrainment connection with a holding body 62' of a pricking element 8', whereby the pushing spring 52' is put under tension, then the respective safety cap means 64' which is held in a form-fitting manner in the radial direction cannot follow the movement and the weakened area 72' between the is broken through. As soon as the free pointed end 65' of the pricking element 8' is released from the safety cap means 64', the pricking element is moved into the disposal position 103' (as described above) under the action of the strap-shaped elastic tongue 98'. The pricking element 8' together with the holding body 62' meanwhile follows the tension movement of the ejector element 50'. The ejector device 10' is then in the activated state and can be operated by pressing the triggering means 56' to execute the puncturing operation.

[000171] Putting the ejector device 10' under tension will now be described. As shown in Figure 46, the plunger-like or ram-like pushing element 50' includes a tension cam 120' which protrudes across the pricking direction. This tension cam 120' passes through a linear preparation 122' which runs in the radial direction in the bottom plate 32' of the housing body 6'. The tension cam 120' therefore protrudes downward beyond the bottom side of the bottom plate 32'. It thereby engages in an opening 124' in the above mentioned disk-shaped component 42' with the operating lever 40' that protrudes

radially. This opening forms a cam guidance curve 126' such that the tension cam 120' is shifted radially inward along this cam guidance curve 126' when the disk-shaped component 42' is rotated. By swiveling the operating lever 40', which protrudes radially, in the direction of the arrow 128' (Figure 45), the pushing element 50' is moved radially inward against the force of the pushing spring 52' over the cam guidance curves 26' and the tension cam 120' until a catch arm 130' of the triggering means 56' engages in a catch recess 132' in the section of the ejector element 50' which has a larger diameter and holds the ejector element 50' at first in the tense state. When the operating lever 40' is released, it returns to the starting position as illustrated in Figure 45 under the influence of the restoring spring 46' mentioned above (Figure 36). As mentioned above, the operating lever 40' and the disk-shape component 42' form a tension means 48' for the ejector device 10'.

A web 134' on the disk-shaped component 42' extending in the [000172] circumferential direction can be seen in Figure 48, said component being elastically deflectable slightly in the axial direction with respect to the plane of the component 42' (see arrow 138) because of a slot-shaped dividing line 136' which also extends essentially in the circumferential direction. On the free end of the web 134' a shoulder 140' which protrudes in the axial direction is formed, engaging in its interior, as illustrated in Figure 45, through a slot-shaped recess 142' which extends in the circumferential direction in the floor 32' of the housing body 6'. This shoulder 140' moves along this slot-shaped recess 142' when the operating lever 40' of the component 42' is pivoted. Then the shoulder 140' is in rotational engagement with the support 14' namely until the web 134' with its shoulder 140' slides on the bottom side of the bottom plate 32' of the housing body 6' onto a wedge-shaped ramp means 144' which can be seen in Figure 12 and 13. In this sliding movement the web 134' is deflected downward in the diagram according to Figures 44 and 45 and the shoulder 140' "dips" into the bottom plate 32' and thereby is disengaged from rotational entrainment with the support 14'. Thus the support 14' is transported due to the rotational coupling of the shoulder 140' with the support 14' only in this initial phase of the movement of the operating lever 40'. During this phase, the tension cam 120 is not

yet moved inward in the radial direction! During this initial phase of the movement of the shoulder 140' up to the ramp means 144', by rotating the support 14', an as yet unused pricking element 8' is brought into the working position. Then the holding body 62' with its engagement means 118' arranged on the inside radially is rotated into the coupling area 116' of the pushing element 50'. The opening 124' in the disk-shaped component 42' is then designed and arranged in such a way that the tension cam 120 of the pushing element 50' cooperates with the cam guidance path 126' at the moment when the next following holding body 62' enters the coupling area 116' of the pushing element 50' and is not transported further with it. In this position, the pushing element 50' is pulled radially inward together with the holding body 62' and the pricking element 8' until the catch arm 130' engages with a catch hook in the catch recess 132' of the pushing element 50' by sliding along the tension cam 120' along the cam guidance curve 126'. As already described above, during the tension process of the ejector device 10' the weakened area 70' between the holding body 62' and the safety cap means 64' is broken and the safety cap means is moved into the disposal position 103' shown in Figure 43' [sic] so that the path of movement for the pricking element 8' is released. Then if the ejector device 10' is operated via the triggering means 56', the pushing element 50' together with the holding body 12' and the pricking element 8' are ejected outward in the radial direction and the free end 65' of the pricking element 8' is ejected extremely briefly beyond the stop position 60' on the outside of the housing body 6' to be able to penetrate into the surface of the skin of a user for an extremely short period of time. During this pricking operation, the retraction spring 54' is under tension and then moves the holding body 62' together with the pricking element 8' rapidly back into the interior of the housing body 6'. The spreadable web 74' then also supports the correct positioning of the used pricking elements 8' on the support 14' and prevents used pricking elements together with holding bodies 62' from slipping out of the guide recesses in the support 14' in the radial direction when a used support cassette is replaced with a new one, which thereby ensures safety disposal of used pricking elements.

[000173] Figure 49 shows a view of the bottom side of the bottom plate 32' of the housing body 6', i.e., without the covering part 44' on the bottom as illustrated in Figure 36.

Thus, on the whole this invention makes available a pricking device with [000174] miniaturized pricking elements, thereby making it possible to design the pricking device in the manner and size of wristwatch to be worn on a user's wrist. The pricking device may also be integrated into a blood analyzer or it may have the components of a blood analyzer of the type described above. The pricking device includes a plurality of pricking elements, in particular between five and twelve, which are inserted as a cassette on the support 14' into the housing body 6'. To do so a user flips open the cover part 4' and places a support cassette in the interior, paying attention to certain orientation marks. The cover part 4' is then closed and a first pricking element 8' is brought into the working position via the operating lever 40'. In doing so, the pricking element 8' and/or its housing body 62' is brought into an entrainment coupling with the pushing element 50' and is pulled radially inward following that. In this process, the safety cap means 64' on the free end 65' if the pricking element 8' is separated and is brought into a disposal position 103' on the support 14' across the pricking direction 12'. When the pricking device 10' activated in this way is released, the pushing element 50' together with the molding body 62' and the pricking element 8' is accelerated suddenly in the radial direction by the release of the pushing spring 52' and is thus brought again into the starting position by means of the recoil spring 54'. By operating the operating lever 40' again, the support 14' is again rotated beyond the shoulder 140', i.e., the used pricking element is rotated out of the working position and a pricking element that has not yet been used is brought into the working position, etc. When all the pricking elements have been used, the support 14' cannot be moved further because of a stop, and the user is notified in this way that a new cassette with new pricking elements must be inserted.